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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,684	10/17/2003	Hiroki Fujihira	NANP113US	9339

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EXAMINER	
CEPERLEY, MARY	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 01/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/687,684	FUJIHIRA ET AL.	
	Examiner	Art Unit	
	Mary (Molly) E. Ceperley	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-6 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) 6 is/are allowed.

6)☒ Claim(s) 1-5 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1) The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2) Claims 2 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) In claim 2, the use of the term "allowing the formation of an immunocomplex between dioxins in the sample and the competitive antigen for dioxin, and the anti-dioxin antibody" is confusing since it is unclear exactly which components join to form the "immunocomplex". It is suggested that language be used that indicates that *two* immunocomplexes are formed, i.e. one complex composed of the "anti-dioxin antibody" and the "competitive antigen for dioxins" and one composed of the "anti-dioxin antibody" and the "dioxins in the sample" (similar language need in the last three lines of the claim). See a similar problem in claim 4.

b) The claim is incomplete in not reciting a step whereby the "determining" of (one or more?) "immunocomplexes" is correlated with "determining an amount of dioxins in a sample". See also, the same problem in claim 4.

c) In claim 4, the use of the term "Z" defined as "a label" is inconsistent with the fact that the compound of formula (II) is defined as an "antigen" earlier in the claim. A "label" is conventionally used in the formation of a "tracer" (labeled hapten) while a "carrier" (i.e. immunogenic carrier) is used in the formation of an "antigen" (the conjugate of a hapten with a carrier).

3) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5) Claim 1 is rejected under 35 U.S.C. 103(a) as being obvious over Kawada et al (HCAPLUS 1998: 239541 describing JP 10101615).

The compound of formula II of Kawada et al wherein B = $(CH_2)_3$ is an obvious structural homologue of the corresponding $(CH_2)_{5\text{-}10}$ compounds of formula (I) of claim 1 {see the $(CH_2)_n$ moiety of the compound of claim 1 wherein n = 5-10}. Given the close structural similarity with the compounds of the prior art, the claimed compounds would be expected to have similar properties to the prior art compounds. See MPEP 2144.09.

6) Claim 3 is rejected under 35 U.S.C. 102(b)/103(a) as being anticipated by or obvious over Kawada et al (HCAPLUS 1998: 239541 describing JP 10101615).

The compound of formula (II) of claim 2 {the immunogen} wherein n = 1 is anticipated by the formula II compound of Kawada et al wherein B = CH_2 as described by the first formula of page 61 wherein the carboxylic acid is conjugated with either BSA or KLH to form the immunogenic conjugate {"conjugates with BSA or keyhole limpet hemocyanin"}. The well known reaction between the carboxylic acid group of the Kawada et al activated hapten and an amine group of either BSA or KLH (both well

known immunogenic peptides) results in the formation of an amide bond (-CONH-) corresponding to the amide bond shown in the structure of formula (II) of claim 3.

The immunogen of claim 3 wherein n = 3 is either anticipated by or rendered obvious by the corresponding immunogen of Kawada et al, the compound of formula II conjugated to BSA or KLH, wherein B = $(CH_2)_3$.

The immunogens of claim 3 formula (II) wherein in n = 2 and 4-10 are rendered obvious by the corresponding structural homologues of the immunogens of Kawada et al formula II wherein B = CH_2 or $(CH_2)_3$. Given the close structural similarity with the compounds of the prior art, the claimed compounds would be expected to have similar properties to the prior art compounds. See MPEP 2144.09.

7) Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kawada et al (HCAPLUS 1998: 239541 describing JP 10101615).

Kawada et al is applied for its description of compounds as discussed in paragraphs ***5)*** and ***6)*** above. The packaging of conventional reagents in kit form, as claimed, is an obvious expedient for ease and convenience in the performance of an assay such as the assay for 2,4,5-T described by Kawada et al. The recited use limitation of claim 5 {"is used as"} is not a limitation on the "kit" *per se*, i.e. the kit is comprised of a compound of formula (I) or formula (II).

Applicant's arguments filed November 14, 2005 (Remarks, the paragraph bridging pages 8 and 9) have been fully considered but they are not persuasive for the reason that the comments are related to a method of use rather than the composition *per se*. As discussed above, the recited use limitation of the claim is not a limitation on the composition *per se*.

8) Claim 6 would be allowable if rewritten to include all of the limitations of the base claim 5.

9) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mary E. Ceperley

January 10, 2006

Mary (Molly) E. Ceperley
Primary Examiner
Art Unit 1641